ISO IDMP will transform your regulatory IT strategy

By Dr. Dieter Schlaps and Dr. Niels Buch Leander

ISO IDMP is the next wave in the pharmacovigilance legislation after xEVMPD. But with a global scope and requiring data integration from the entire company it is a much bigger wave. In 2012, the five ISO standards referred to as "ISO IDMP" were approved. Their purpose is to standardise the identification of medicinal products, ultimately leading to improved pharmacovigilance across products, companies and jurisdictions. It has a global scope and in Europe for instance it will take effect by 2016.

2016 is by no means far away when planning to be compliant with ISO IDMP. Although the implementation guides and messaging standards for ISO IDMP are still to be seen, one thing is clear already: Being globally compliant with the ISO IDMP standards will require more than just an isolated solution. On the contrary, the entire IT landscape across the different divisions in the pharmaceutical company will have to be considered, and integration will have to be planned. Your IT strategy should plan for this already now.

The challenges ahead

Any change in a regulated company is naturally a challenge. In the case of ISO IDMP the challenge is even greater. First of all, because the regulators' plans are not entirely clear, and even when the implementation plans become available, much will rely not just on the overall ICH guidance, but on regional guidance that can be difficult to track and maintain. With parallel regional implementations of differing scope and timelines, it will be a challenge alone to manage the portfolio of ISO IDMP implementations. Moreover, the breadth of data contributors to the IDMP product information is overwhelming, from Regulatory Affairs to Pharmacovigilance to Clinical Trials, Marketing and Product Supply. Finally, the data source may not be ready.

For instance, much product information is stored in documents, and this information needs to be made available as data that can be managed and submitted. In conclusion, the challenge of ISO IDMP is on an entirely different scale from xEVMPD, and it will be necessary to look simultaneously at the data process and data accessibility as well as at the IT landscape that should be prepared to deal with this daunting data task.

ISO IDMP may also offer opportunities

Although ISO IDMP is first and foremost a regulatory challenge, an early start will allow a company to identify the opportunities that also arise when the data landscape is being analysed and transformed. In other words, it is a good time to plan for a strategic solution to ISO IDMP. In fact, due to their global scope, the ISO IDMP standards can be treated as an extensive and consistent data model for the entire IT landscape. One advantage is for instance that ISO IDMP offers vocabularies that are maintained externally and not in the company alone. Using a data model may yield a number of benefits as systems are streamlined against each other with the opportunity to automate integration.

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The idea of an ISO IDMP data warehouse

By using the ISO IDMP standards as the company's data model, the company can build a data warehouse with data stemming from various company repositories. In this way, there is one authoritative repository for the product information, which can then be used both inside the company and submitted externally to the authorities. This means that existing applications may be retained, and yet it offers the opportunity to establish integration points that can eliminate double data entry. Moreover, a data warehouse offers reporting and business intelligence opportunities that have hitherto not been possible in the Regulatory Affairs IT landscape. For instance, future regulatory requirements may be met by simply changing the reporting requirements rather than having first to locate and make data accessible from various sources before setting up a new report or application. Also, the data in the central data warehouse will enable KPI monitoring of the entire value chain in a regulatory change, from change request to batch release.

What now? Starting the ISO IDMP analysis

The time is right for starting strategic considerations of the ISO IDMP data flow in your company. ISO IDMP is part of legislation and will come into effect, even if the precise implementation scope may still shift. Therefore, it is important that you have analysed the aspects that will be important in an integrative and well-defined solution to ISO IDMP.

For an initial ISO IDMP analysis, NNIT suggests four parallel streams:

1. **Business Information Modelling.**
   The first stream in the analysis serves to obtain a mutual understanding of the regulatory requirements and the ISO IDMP standard. Moreover, it is crucial to identify ISO IDMP's key role in the definition of a future Regulatory Information Management Solution environment. Important outputs are: a communication strategy, a business case, information variables, information sources with assessment and business rules
2. **User Requirements.**
   This stream defines the high-level requirements for the presentation of RIM information, including the functional, visual, navigational and reporting aspects of the solution. Important outputs are usability requirements and design guidelines.
3. **Application Architecture.**
   This stream describes the current regulatory application landscape and lays out a high-level approach for data storage and distribution. Important outputs are: application goals, current RIM application landscape, draft data storage and distribution approach
4. **Project Scope Definition.**
   This stream focuses on creating a first release plan for the solution and associating each release with the business goals to be achieved. The plan will include business goals, business interactions and business processes

Analysis – design – build

With a solid analysis of the challenges as well as the opportunities that lie ahead, it is possible to design and build the solution that both makes ISO IDMP compliance possible and prepares Regulatory Affairs IT for having complete insight into the regulatory activities, with the opportunity of eliminating administrative bottlenecks and meeting future regulatory requirements with a solid data management approach.

For further information about the next steps for ISO IDMP and an integrative RIMS solution, please contact: Dr. Dieter Schlaps on dscp@nnit.com and +49 162 937 29 72 or Dr. Niels Buch Leander on nbln@nnit.com and +45 30755339.

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